



# CDC Surveillance of FDA-Regulated Products

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CDC Surveillance of FDA-Regulated Products

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Food and Drug Law

Mr. Peter Barton Hutt

I. Introduction

A primary aspect of the Centers for Disease Control and Prevention's (CDC) mission is to monitor health.<sup>1</sup> One of the ways in which the CDC performs this task is by setting up surveillance systems that monitor a wide range of health issues, from the incidence of illness to adverse reactions to vaccines. In this paper, various surveillance systems that the CDC has established to monitor the effects of FDA-regulated products will be discussed. Most of this surveillance of FDA-regulated products is indirect. The CDC typically studies illnesses or reactions resulting from use of the FDA-regulated product, it studies the effects of the product, not the product itself. These effects vary from cases of foodborne illness to increased antimicrobial resistance. The primary focus of this paper on the CDC surveillance efforts in this area is on the surveillance

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<sup>1</sup>Centers for Disease Control and Prevention, About CDC, at <http://www.cdc.gov/aboutcdc.htm> (last visited March 7, 2003).

of foodborne illness. These surveillance systems are not perfect, and various problems and deficiencies with the systems will also be discussed.

## II. Surveillance of Foodborne Illnesses

The Centers for Disease Control and Prevention (CDC) estimated in 1999 that foodborne illnesses cause 5,000 deaths in the United States each year.<sup>2</sup> The danger posed by the pathogens that cause foodborne illnesses is increasing. New pathogens are constantly being discovered, and those we already know about are growing increasingly resistant to treatment.<sup>3</sup> Although the American food supply is one of the safest in the world, these pathogens create a worrisome threat, particularly as Americans' eating habits lead them more and more to processed foods and sizable portions of the population increase in age, which increases the susceptibility of Americans to these pathogens.<sup>4</sup> Over time, it appears that the CDC's surveillance systems might have helped reduce the amount of foodborne illness in the United States. In 2002, Health and Human Services Secretary Tommy Thompson announced that, according to CDC, there was "a 23 percent overall drop in bacterial food borne illnesses since 1996."<sup>5</sup> The 1996 start date was presumably used for comparison because FoodNet was started in 1996.<sup>6</sup> Despite this drop, the CDC's surveillance systems need further development. Of the 76 million cases of foodborne illness that the CDC estimates occur in the United States

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<sup>2</sup>Centers for Disease Control and Prevention, Office of Communication, CDC Data Provides The Most Complete Estimate On Foodborne Disease in the United States, September, 16, 1999 at <http://www.cdc.gov/od/oc/media/pressrel/r990917.htm> (last visited March 7, 2003).

<sup>3</sup>*Id.*; Robert V. Tauxe, *Emerging Foodborne Diseases: An Evolving Public Health Challenge*, 3 EMERGING INFECTIOUS DISEASES 425, 426 (October-December 1997), available at <http://www.cdc.gov/ncidod/eid/vol3no4/adobe/tauxe.pdf> (last visited March 7, 2003).

<sup>4</sup>Centers for Disease Control and Prevention, Office of Communication, CDC Data Provides The Most Complete Estimate On Foodborne Disease in the United States, *supra* note 2.

<sup>5</sup>Melinda Hemmelgarm, New Data Show Decline In National Food Borne Illness, Human Environmental Sciences Extension's Resource: University of Missouri-Columbia, at <http://outreach.missouri.edu/hesnutrnews/safe4-19-02.htm> (last visited March 7, 2003).

<sup>6</sup>*Id.*

each year, only 13.8 million of those cases have been linked to known pathogens.<sup>7</sup> These numbers clearly indicate major gaps within the CDC's surveillance systems and the room for improvement in identifying and conducting surveillance of foodborne illnesses.<sup>8</sup>

The CDC falls under the authority of the United States Department of Health and Human Services.<sup>9</sup> Most of the CDC's foodborne illness surveillance efforts fall under the auspices of the Foodborne and Diarrheal Diseases Branch of the CDC.<sup>10</sup> This branch not only oversees the efforts of surveillance systems like FoodNet and PulseNet, but also assists in the investigation of outbreaks of illness, conducts research and consults with state and local public health departments.<sup>11</sup>

Over the last several years, the role of the CDC in surveillance of foodborne illness in the United States has increased. One incident which demonstrated the increased need for CDC surveillance were outbreaks of the parasitic pathogen *Cyclospora cayetanensis* in 1996 and 1997 resulting from the importation of raspberries from Guatemala.<sup>12</sup> The importation of the raspberries was suspended and surveillance also helped to detect the pathogen in mesclun lettuce and basil.<sup>13</sup>

The increase in surveillance stemmed in large part from the Clinton Administration's National Food Safety Initiative, which was introduced in 1997.<sup>14</sup> Two of the primary surveillance organizations that the CDC helps operate are FoodNet and PulseNet, both of which predate the National Food Safety Initiative. FoodNet, is a network made up of the CDC, sites in nine states of the CDC's Emerging Infections Program, the U.S.

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<sup>7</sup>Martin Wiedmann, *Methods In Nutrition Science – Subtyping Of Bacterial Foodborne Pathogens*, NUTRITION REVIEWS, July 1, 2002, available at 2002 WL 11792192.

<sup>8</sup>*Id.*

<sup>9</sup>Centers for Disease Control and Prevention, About CDC, *supra* note 1.

<sup>10</sup>Centers for Disease Control and Prevention, Division of Bacterial and Mycotic Diseases, Foodborne and Diarrheal Diseases Branch, at <http://www.cdc.gov/ncidod/dbmd/foodborne/index.htm> (last visited March 7, 2003).

<sup>11</sup>*Id.*

<sup>12</sup>Robert V. Tauxe, *New Approaches to Surveillance and Control of Emerging Foodborne Infectious Diseases*, 4 EMERGING INFECTIOUS DISEASES 455 (July-September 1998), available at <ftp://ftp.cdc.gov/pub/EID/vol4no3/adobe/tauxe.pdf> (last visited March 7, 2003).

<sup>13</sup>*Id.* at 455.

<sup>14</sup>Corrections, President's National Food Safety Initiative, 63 Fed. Reg. 45,922, 45,922 (August 27, 1998); Tauxe, *New Approaches to Surveillance and Control of Emerging Foodborne Infectious Diseases*, *supra* note 12, at 455.

Department of Agriculture (USDA), and the Food and Drug Administration (FDA).<sup>15</sup> Another network, PulseNet, is also made up of the CDC and a system of state public health laboratories in all fifty states, five local public health laboratories, the USDA FSIS laboratory and seven FDA laboratories.<sup>16</sup> PulseNet handles molecular subtyping, whereas FoodNet concentrates on antimicrobial resistance.<sup>17</sup> CDC's role in analyzing data from the surveillance networks is "to (1) monitor national health trends, (2) formulate and implement prevention strategies, (3) evaluate state and federal disease prevention efforts, and (4) identify outbreaks that affect multiple jurisdictions...."<sup>18</sup>

A crucial aspect to consider when looking at the CDC's role in surveillance and in food safety overall is that the "CDC is not a regulatory agency."<sup>19</sup> The CDC lacks the ability to make regulations that would bring about improvements in reducing the amount of foodborne illness, and is reliant on agencies such as the FDA and the USDA to enact specific policies.<sup>20</sup> However, the information and advice that the CDC shares with these agencies and others may have an impact upon the policies and regulations that those agencies develop.<sup>21</sup> For instance, it is through the use of surveillance that the FDA may see the impact that its regulations have. If the FDA institutes a number of regulations meant to curb the spread of *Campylobacter*, and in resulting studies the CDC shows that its surveillance data indicates a reduction in infections resulting from *Campylobacter*, then the FDA can perhaps try to establish if there is a causal relationship between that data and its regulations.<sup>22</sup> At the same time, surveillance data may also seem to suggest that certain

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<sup>15</sup>Centers for Disease Control and Prevention, FoodNet, What is FoodNet? at <http://www.cdc.gov/foodnet/what.is.htm> (last visited March 7, 2003).

<sup>16</sup>Centers of Disease Control and Prevention, PulseNet: The National Molecular Subtyping Network for Foodborne Disease Surveillance, at <http://www.cdc.gov/pulsenet/> (last visited March 7, 2003).

<sup>17</sup>Tauxe, *New Approaches to Surveillance and Control of Emerging Foodborne Infectious Diseases*, *supra* note 12, at 455.

<sup>18</sup>U.S. General Accounting Office, Report to the Chairman, Committee on Agriculture, Nutrition, and Forestry, U.S. Senate: Food Safety: CDC Is Working to Address Limitations in Several of Its Foodborne Disease Surveillance Systems, GAO-01-973 Food Safety Surveillance (Sept. 2001), at 6, *available at* <http://www.gao.gov/new.items/d01973.pdf>.

<sup>19</sup>Centers for Disease Control and Prevention, Foodborne Infections, What is CDC Doing to Control and Prevent Foodborne Disease?, at <http://www.cdc.gov/ncidod/dbmd/diseaseinfo/foodborneinfections.g.htm> (last visited March 7, 2003).

<sup>20</sup>*Id.*

<sup>21</sup>*Id.*

<sup>22</sup>*Id.*

regulations have been ineffective, when the data shows no decline, or perhaps even an increase in infections.<sup>23</sup>

### A. FoodNet

The Foodborne Diseases Active Surveillance Network, (FoodNet) is the primary network that the CDC uses in conducting surveillance of foodborne illnesses, many of which result from consumption of FDA-regulated products. FoodNet is part of the CDC's Emerging Infections Program (EIP).<sup>24</sup> As noted above, the CDC is not the sole agency involved in FoodNet: the FDA, USDA and sites in 9 states also participate.<sup>25</sup> In fact, this participation is essential to the operation of the network. FoodNet predates the National Food Safety Initiative, having started in 1995, and it has expanded in size since then.<sup>26</sup>

FoodNet's objectives are to "accurately estimate the burden of foodborne disease in the United States, investigate the sources of infection in outbreaks and sporadic cases, and build public health infrastructure for dealing with emerging foodborne disease issues."<sup>27</sup>

FoodNet is unique because it engages in active, as opposed to passive, surveillance of foodborne illnesses.<sup>28</sup>

Instead of waiting for laboratories to report findings of different foodborne illnesses to health departments,

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<sup>23</sup> *Id.*

<sup>24</sup> Centers for Disease Control and Prevention, FoodNet, What is FoodNet?, *supra* note 15.

<sup>25</sup> *Id.*

<sup>26</sup> *News and Notes, The National Food Safety Initiative*, 4 EMERGING INFECTIOUS DISEASES 347, 348 (April-June 1998) available at <http://www.cdc.gov/ncidod/eid/vol4no2/adobe/new.pdf> (last visited March 7, 2003).

<sup>27</sup> Bala Swaminathan, Timothy J. Barrett, Susan B. Hunter, Robert V. Tauxe and the CDC PulseNet Task Force, *Synopses: PulseNet: The Molecular Subtyping Network for Foodborne Bacterial Disease Surveillance, United States*, 7 EMERGING INFECTIOUS DISEASES 382 (May-June 2001), available at <http://www.cdc.gov/ncidod/eid/vol7no3/pdfs/swaminathan.pdf> (last visited March 7, 2003).

<sup>28</sup> Centers for Disease Control and Prevention, FoodNet, What is FoodNet?, *supra* note 15.

under FoodNet, public health officials are constantly in contact with the labs in order to learn about new outbreaks of foodborne diseases and the information from those labs is reported to the CDC.<sup>29</sup> In addition to the information obtained from the laboratories, FoodNet also includes “case control” studies performed by the CDC as part of FoodNet.<sup>30</sup> These “case control” studies are a clearer display of the role that the CDC plays in surveillance of FDA-regulated products specifically, and not just the spread of pathogens from those products to victims. Under some of the “case control” studies, the CDC actually “examine[s] the association between infections and specific foods.”<sup>31</sup> It is at this point that the surveillance activities that the CDC undertakes are most similar to those undertaken by the FDA when it performs post-market surveillance on products.<sup>32</sup>

By conducting surveillance of FDA-regulated products through FoodNet, the CDC’s efforts differ from those of the FDA or the U.S. Customs Service, in the case of imports. Through FoodNet, the introduction of foodborne pathogens through food products is usually only detected once the pathogens are found in stool samples, that clinical laboratories then analyze, and then report their findings back to CDC.<sup>33</sup> Thus, although FoodNet conducts active surveillance of the foodborne illnesses themselves, it is conducting, in a sense, an indirect form of surveillance of the food products that cause those illnesses. FoodNet uses a variety of sources of information in compiling its data. Although FoodNet largely relies on the information from the laboratories to detect foodborne illness, its monitoring activities also include the aforementioned CDC case studies and laboratory and physicians surveys conducted by FoodNet in an attempt to collect information about the process of how both laboratories and physicians treat and evaluate foodborne diseases.<sup>34</sup>

From its beginning, FoodNet helped provide immediate dividends to the public health. It identified *Campy-*

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<sup>29</sup>*Id.*

<sup>30</sup>General Accounting Office, *supra* note 18, at 9.

<sup>31</sup>*Id.* at 9.

<sup>32</sup>*Id.* at 8.

<sup>33</sup>Centers for Disease Control and Prevention, FoodNet, What is FoodNet?, *supra* note 15.

<sup>34</sup>General Accounting Office, *supra* note 18, at 45.

*lobacter* as the “most common cause of foodborne disease” and assisted investigations into *Listeriosis* found in hot dogs and *Salmonella* found in toasted oat cereal.<sup>35</sup> By 2000, the increased surveillance by FoodNet had helped contribute to a “25 percent decline between 1998 and 1999 in the number of *E. coli* O157:H7 infections; a 41 percent drop in the incidence of *Shigella* infections; and a 19 percent decline in the number of illnesses caused by *Campylobacter*.”<sup>36</sup>

FoodNet does suffer from gaps in its surveillance system. One of the largest gaps is that the system only incorporates information from patients who have gone to see a doctor, and from whom samples have been sent to laboratories.<sup>37</sup> If, as with many cases of foodborne illness, the patient never goes to see a doctor, then FoodNet has no way of knowing about their illness.<sup>38</sup> A General Accounting Office report cited a CDC-sponsored study that showed that in only 7% of 340 million cases of people who suffer from acute diarrheal illness each year do people seek treatment.<sup>39</sup> Thus, although FoodNet does mark a shift away from ‘passive’ surveillance of foodborne illness, these systems of surveillance will always incorporate some aspect of passivity. Monitoring of foodborne illnesses will always be reliant on victims taking some steps to receive medical attention for their illness.

Some might argue that this is not a crucial factor, with regards to the notion that if a victim does not seek medical attention, then obviously the illness from which they suffer is not that severe and perhaps not a priority for surveillance. Therefore, FoodNet would be more effective and efficient in spending its resources monitoring those illnesses for which medical attention has been sought. One small problem with

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<sup>35</sup>Department of Health and Human Services, HHS Fact Sheet, HHS Initiatives To Reduce Foodborne Illness, March 16, 2000, at <http://www.cfsan.fda.gov/~lrd/hhsfsi2.html> (last visited March 7, 2003); News and Notes, The National Food Safety Initiative, *supra* note 26.

<sup>36</sup>Department of Health and Human Services, *supra* note 35.

<sup>37</sup>*Foodborne Illness In United States On A Decline*, FOOD & DRINK WEEKLY, Apr. 29, 2002, available at 2002 WL 9681141.

<sup>38</sup>*Id.*

<sup>39</sup>General Accounting Office, *supra* note 18, at 7.



this approach is that the decision not to seek medical attention is not always directly linked to the severity of the illness, although that likely is the scenario in a majority of cases. Gaps of this type may exist within FoodNet's surveillance of cases of even severe diseases.

Another gap in the FoodNet surveillance system takes place at the point where victims of foodborne illness seek medical attention. The fact that foodborne illnesses sometimes may not be correctly diagnosed, means that even if a victim of foodborne illness seeks medical attention, if a doctor does not correctly diagnose the illness, samples from that patient may never make their way into the FoodNet system.<sup>40</sup> So, the cases of foodborne illness that the CDC is able to trace through FoodNet are a subset of all cases of foodborne illness.<sup>41</sup> They are those cases in which the victim has sought medical attention, the physician or their corresponding public health laboratory have correctly diagnosed the illness and that information has been sent along by one of the nine EIP state sites working in conjunction with FoodNet.<sup>42</sup> Although these factors do limit the range of FoodNet, the system still tracks a sizable number of cases of foodborne illness.

The FoodNet system was cited in a Government Accounting Office report for failing to report information from the "case control" studies it has performed, even though it does publish other information annually.<sup>43</sup> The reporting of information is, of course, crucial to the success of a system that has as one of its major goals the sharing of information.

## B. PulseNet

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<sup>40</sup>*Foodborne Illness In United States On A Decline*, *supra* note 37.

<sup>41</sup>Centers for Disease Control and Prevention, *Incidence of Foodborne Illnesses: Preliminary Data from the Foodborne Disease Active Surveillance Network (FoodNet) United States, 1998*, CDC MORTALITY AND MORBIDITY WEEKLY REPORT, Mar. 12, 1999, 189, 193, available at <http://www.cdc.gov/mmwr/PDF/wk/mm4809.pdf> (last visited March 7, 2003).

<sup>42</sup>*Foodborne Illness In United States On A Decline*, *supra* note 37.

<sup>43</sup>General Accounting Office, *supra* note 15, at 13-14.

Another major surveillance system put together by the CDC is PulseNet. PulseNet is a nationwide network of public health laboratories that uses bacterial subtyping or “DNA fingerprinting” to help identify outbreaks of foodborne illness.<sup>44</sup> How does the scientific process of DNA fingerprinting work? The fingerprinting process is another name for bacterial subtyping. In this process, the laboratories look at bacterial isolates, and then try to determine if the isolates have a “very recent . . . common ancestor.”<sup>45</sup> This is possible because when the bacteria reproduce, the new bacteria are virtually identical to their ancestors.<sup>46</sup> These similarities allow the laboratories to see a number of similarities between bacterial isolates from multiple subjects and link them to a common ancestor.<sup>47</sup> The samples taken by PulseNet are not simply bacterial isolates from individual patients, but also bacterial isolates from contaminated food products, another way in which the CDC conducts not just indirect, but direct surveillance of FDA-regulated products.<sup>48</sup>

Nationwide surveillance programs such as PulseNet, are most helpful in identifying “outbreaks of rare foodborne diseases that occur over a wide geographic and temporal range and are consequently difficult to detect by classical epidemiologic approaches and surveillance systems.”<sup>49</sup> Martin Wiedmann notes in his article “Methods In Nutrition Science – Subtyping Of Bacterial Foodborne Pathogens”, the example of a type of listeriosis that is both rare and which has a substantial incubation period.<sup>50</sup> Wiedmann predicts that whereas pulsed-field gel electrophoresis (PFGE) subtyping is now a highly used approach to bacterial subtyping and is the process used by PulseNet, DNA sequencing-based subtyping is the wave of the future.<sup>51</sup> This is so because using a DNA sequencing-based approach creates “sequence data [that is]... considerably less am-

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<sup>44</sup>Wiedmann, *supra* note 7; Centers for Disease Control and Prevention, What is PulseNet?, at [http://www.cdc.gov/pulsenet/what\\_is.htm](http://www.cdc.gov/pulsenet/what_is.htm) (last visited March 7, 2003).

<sup>45</sup>Wiedmann, *supra* note 7.

<sup>46</sup>*Id.*

<sup>47</sup>*Id.*

<sup>48</sup>General Accounting Office, *supra* note 18, at 10.

<sup>49</sup>Wiedmann, *supra* note 7.

<sup>50</sup>*Id.*

<sup>51</sup>*Id.*

biguous and easier to interpret than banding pattern-based subtypes obtained through the other DNA-based subtyping approaches....”<sup>52</sup> PulseNet is working to incorporate DNA sequencing-based subtyping into its system and make the information obtained by that method compatible with current data.<sup>53</sup>

The Pulse Net laboratories can do a DNA fingerprint of *E. coli* bacteria, a process that used to take much longer.<sup>54</sup> The benefits of this faster detection are clear. State and local public health agencies can match the *E. coli* bacteria with that from other patients, discovering the possibility of a common source between two or more patients, and using information obtained from those patients, track down the source. The increased speed in detection is quite important because the faster the source of the bacteria is detected, the faster it can be removed from the market. Earlier warnings to the media can reduce the amount of human consumption of the product. Whereas an outbreak may have had days or weeks to continue to infect the populace without public knowledge in the past, under the new system, local health agencies can alert the public and other public health agencies in a shorter period of time. The number of lives saved, illnesses prevented, and dollars saved for the economy may be quite sizable. A request by a number of state and local public health laboratories in a General Accounting Office report on CDC’s surveillance systems was direct access to the PulseNet system, which would further speed up the detection process, and which has already been given to some of the laboratories.<sup>55</sup> These are only some of the benefits of improved CDC surveillance of foodborne illness and FDA-regulated products.

One example of the beneficial use of PulseNet was the detection of a *Shigella* outbreak in 1998.<sup>56</sup> Minnesota’s public health laboratory, one of the labs in the PulseNet system, was monitoring two *Shigella*

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<sup>52</sup>*Id.* (citations omitted).

<sup>53</sup>Bala Swaminathan, Timothy J. Barrett, Susan B. Hunter, Robert V. Tauxe and the CDC PulseNet Task Force, *supra* note 27, at 388.

<sup>54</sup>Centers for Disease Control and Prevention, Office of Communication, CDC Data Provides The Most Complete Estimate On Foodborne Disease in the United States CDC, *supra* note 2.

<sup>55</sup>General Accounting Office, *supra* note 18, at 14; Bala Swaminathan, Timothy J. Barrett, Susan B. Hunter, Robert V. Tauxe and the CDC PulseNet Task Force, *supra* note 27, at 384.

<sup>56</sup>Department of Health and Human Services, *supra* note 35.

outbreaks linked to restaurants.<sup>57</sup> Using PulseNet, the Los Angeles public health laboratory was able to quickly contact the Minnesota lab and let them know that they too were investigating *Shigella* outbreaks linked with restaurants.<sup>58</sup> The two labs, with the assistance of the CDC were able to use DNA fingerprinting of the bacteria to discover that the outbreaks were linked and the parties then traced the bacteria to parsley that was used as a garnish in the restaurants.<sup>59</sup> Eventually, the parsley was traced back to its source, a farm in Mexico that agencies then advised on how to prevent further contamination of their crop.<sup>60</sup> Once sources like the one in Mexico are discovered, many actions may be taken, including a product recall.<sup>61</sup>

This example helps illustrate the process of working backwards to discover the source of foodborne illness and then take action to prevent further contamination at the source. The focus of this paper however is on the initial surveillance activities that alert agencies to a problem. The links between the Minnesota and Los Angeles laboratories display the importance of national surveillance networks. Absent PulseNet, weeks and months may have passed before the different public health labs were aware that each was dealing with *Shigella* outbreaks, if indeed they ever became aware of it. By linking the two and discovering through the DNA fingerprinting that the two outbreaks were linked, the public health laboratories could then narrow down the number of possible sources to those products that were common amongst the restaurants to which the outbreaks were linked.<sup>62</sup> In this case, it turned out to be the parsley used as a garnish. Without the ability to narrow down the list of possible sources with the information from other public health agencies, the investigation may have taken far longer to identify the parsley as the culprit.

Much like FoodNet, PulseNet's nationwide coverage enables it to detect widespread outbreaks through the United States. In helping to identify a multi-state outbreak of *Salmonella* in toasted oat cereal, PulseNet

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<sup>57</sup> *Id.*

<sup>58</sup> *Id.*

<sup>59</sup> *Id.*

<sup>60</sup> *Id.*

<sup>61</sup> General Accounting Office, *supra* note 18, at 52.

<sup>62</sup> Bala Swaminathan, Timothy J. Barrett, Susan B. Hunter, Robert V. Tauxe and the CDC PulseNet Task Force, *supra* note 27, at 386.

managed to help identify the presence of the bacteria in 20 different states.<sup>63</sup> Although this does indicate that the bacteria had managed to spread over a wide region due to the distribution of the source, PulseNet enabled public health officials to discover that the multiple outbreaks were linked.<sup>64</sup>

PulseNet has not gone without criticism and there is apparently still plenty of room for improvement with CDC's system. PulseNet only uses one pathogen fingerprinting system, and while that system is the "most broadly applicable method... [other] labs use about a dozen other methods to test for different organisms."<sup>65</sup> Other criticisms of PulseNet include the fact that CDC has very rigid standards for all laboratories that wish to be a part of the system, limiting its expansion, and the fact that it takes the CDC "a minimum of 24 hours to respond" to the labs.<sup>66</sup> How much this time delay could be reduced remains to be seen. Time delays for a surveillance system such as PulseNet are critical, as it is geared towards rapid dissemination of information, and further delays might allow for "secondary or tertiary transmission" of illness.<sup>67</sup> The CDC realizes that PulseNet is not a perfect system, and has made use of the assistance of other fingerprinting systems in conducting surveillance of foodborne illness. One of those is a "Web-based library" of fingerprints called PathogenTracker, created by Cornell University faculty and students.<sup>68</sup> That website assisted PulseNet and the CDC in 1998 in helping to track down a deadly *Listeria* outbreak.<sup>69</sup>

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<sup>63</sup>U.S. Food and Drug Administration, Statement of Bernard A. Schwetz D.V.M., Ph.D., Acting Principal Deputy Commissioner, Food and Drug Administration, Before the Committee on Governmental Affairs, Subcommittee on Government Management, Restructuring and the District of Columbia, October 10, 2001 at <http://www.fda.gov/ola/2001/foodsafety1010.html> (last visited March 7, 2003).

<sup>64</sup>*Id.*

<sup>65</sup>David Cameron, *Food-Borne Bug Hunter*, TECHNOLOGY REVIEW, February 1, 2002, at <http://www.technologyreview.com/articles/cameron020102.asp> (last visited March 7, 2003).

<sup>66</sup>*Id.*

<sup>67</sup>Douglas N. Klaucke, James W. Buehler, Stephen B. Thacker, R. Gibson Parrish, Frederick L. Trowbridge, Ruth L. Berkelman, and the Surveillance Coordination Group, *Guidelines for Evaluating Surveillance Systems*, CDC MORBIDITY AND MORTALITY WEEKLY REPORT, May 6, 1988, available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/00001769.htm> (last visited March 7, 2003).

<sup>68</sup>Cameron, *supra* note 65.

<sup>69</sup>*Id.*

### C. Bioterrorism

The recent increase in possible concerns about bioterrorism bring about added importance to the role of the CDC's surveillance systems. The growing threat of terrorist attacks on domestic targets has led to the Bush Administration's increased concerns about the safety of the American food supply.<sup>70</sup> The Bush Administration requested 104 million dollars for the FDA as part of a 20 billion dollar emergency relief budget request.<sup>71</sup> Of that 104 million dollars, 61 million was to be used to increase inspections of food imports.<sup>72</sup> While part of the money was designated to allow FDA to hire more inspectors and agents to help monitor imports, part of the money was also designated to improving the surveillance activities of the FDA and CDC.<sup>73</sup> Part of the money was to be used to expand FDA information systems, including the eLEXNET system, which would work with PulseNet to better enable the "comparison of bacteria isolated from patients from widespread locations, from foods and from food production facilities."<sup>74</sup>

The case presented earlier of contaminated parsley from Mexico helps show concern about the potential for contaminated imports from abroad. Bacteria in imported food could potentially pose a terrorist threat to the United States if terrorists intentionally contaminate that food. CDC surveillance of the food supply helps put the nation on alert of any emerging outbreaks and could help quickly reduce the impact of any potential attack on the American public through the food supply. It would be incorrect to confine the notion of such a threat solely to imports. This threat of bioterrorism exists with regards to products that might be purposefully contaminated here in the United States.

The CDC's food surveillance success can be seen in the government's willingness to see the system expand

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<sup>70</sup>U.S. Food and Drug Administration, DHHS Requests Over \$104 Million for FDA to Combat Bioterrorism, October 31, 2001 at <http://www.fda.gov/oc/bioterrorism/budget.html> (last visited March 7, 2003).

<sup>71</sup>*Id.*

<sup>72</sup>*Id.*

<sup>73</sup>*Id.*

<sup>74</sup>*Id.*

even further, potentially to help combat bioterrorism. As part of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Congress granted 19.5 million dollars to states and Indian tribes to enable them to create facilities that could conduct food surveillance and presumably to be part of both FoodNet and PulseNet, among other systems.<sup>75</sup> The value of the surveillance systems is demonstrated by the fact that members of Congress saw fit to include the expansion of the surveillance systems as part of a bioterrorism bill. This is a tacit recognition that the dangers that FoodNet and PulseNet alert public health officials to may not just be incidents of accidental contamination of the food supply, but rather purposeful contamination of the food supply. The first indications that the United States has fallen victim to such an attack may result from the findings of public health agencies in conjunction with the CDC using the PulseNet system to identify outbreaks that may occur on a nationwide scale. In a sense, the surveillance data will help bring about investigations of common sources that not only involve the FDA and USDA, but also have national security implications that will involve a number of other government agencies, including the intelligence community and the military. It is not clear if concerns about bioterrorism may lead the CDC to increase the number of different types of bacteria that are currently tracked by the surveillance systems, perhaps to make some type of adjustments to consider those types of bacteria that might likely be used in such an attack. Congress, of course, included several other measures in the recent bioterrorism bill for FDA and other agencies to undertake in preventing contaminated food from ever making it to the market, but the CDC's surveillance systems will keep watch in the possible event that these measures are ineffective in guarding the American public against all such contaminated foods.<sup>76</sup>

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<sup>75</sup> *Breaking Down the Bioterrorism Bill*, FOOD CHEMICAL NEWS, May 27, 2002, available at 2002 WL 11879342; Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Pub. L. No. 107-188, §317R (2002).

<sup>76</sup> *Breaking Down the Bioterrorism Bill*, *supra* note 75; Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Pub. L. No. 107-188, (2002).

#### D. Imports and International Expansion of Surveillance

Beyond the concerns of bioterrorism, imported foods also pose a threat by the simple fact that many foreign food producers might not undertake the same protections against contamination that American food producers do. Furthermore, imported goods might introduce parasites and bacteria that have evolved outside the United States and which are unfamiliar to the American diet, and perhaps in some cases, the American medical profession. Although many of the steps to deal with these contaminated imports lead beyond the surveillance activities of the CDC, surveillance will likely be the first indication that these foreign contaminants are causing foodborne illness in the United States. This detection of illness by the surveillance systems will help bring about the procedures needed to prevent further consumption of the imports and eliminate contamination of the imports at their source. As noted above with regards to bioterrorism, surveillance is the first line of defense in that it may be the first to identify the pathogens causing outbreaks. Surveillance is also, in another manner, the last line of defense in that it will identify these pathogens only after the contaminated products made it all the way through various customs procedures to finally reach the American market.

The success of PulseNet in the United States has led the CDC to attempt to expand the network globally.<sup>77</sup>

The CDC is working on this project in conjunction with the World Health Organization.<sup>78</sup> PulseNet also has a European counterpart called EuroNet.<sup>79</sup> The two systems have been sharing information since 2001.<sup>80</sup>

This global increase in communication about outbreaks of foodborne illness is particularly valuable when

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<sup>77</sup>U.S. Food and Drug Administration, Statement of Bernard A. Schwetz D.V.M., Ph.D., Acting Principal Deputy Commissioner, Food and Drug Administration, Before the Committee on Governmental Affairs, Subcommittee on Government Management, Restructuring and the District of Columbia, *supra* note 63.

<sup>78</sup>*Id.*

<sup>79</sup>Patricia Simms, *E. Coli Outbreak Prompts Beef Recall; Infection Has Sickened 52 People In Wisconsin*, WISCONSIN STATE JOURNAL, Sept. 28, 2002, available at 2002 WL 24286860.

<sup>80</sup>*Id.*



considering the amount of imported food products consumed by the American public. It also will perhaps better enable public health agencies and the CDC to work with their European counterparts in identifying foreign sources of bacteria and in working to stop contamination of the food supply abroad.

#### E. Other CDC Foodborne Disease Surveillance Systems

Surveillance of diseases is a major task for the CDC, and the CDC conducts, outside of FoodNet and PulseNet, a wide variety of surveillance systems of foodborne illnesses. For example, under the CDC's Emerging Infections Program, are programs such as Active Bacterial Core surveillance (ABCs) which monitor various bacterial diseases.<sup>81</sup> This mission may seem similar to FoodNet's, but FoodNet is specifically designated to more closely focus on foodborne and waterborne disease, particularly a limited number of pathogens.<sup>82</sup> The General Accounting Office in September of 2001 published a report, Food Safety: CDC Is Working to Address Limitations in Several of Its Foodborne Disease Surveillance Systems, that outlined the surveillance systems that the CDC conducted, and also discussed some of the problems and issues with those surveillance systems.<sup>83</sup> Two major surveillance systems the report discussed are the Foodborne Disease Outbreak Surveillance System and the Surveillance Outbreak Detection Algorithm.<sup>84</sup> The Foodborne Disease Outbreak Surveillance System, a passive surveillance system, performs the function that its name indicates, it conducts surveillance of foodborne disease outbreaks across the country.<sup>85</sup> The types of sources to which it has helped trace outbreaks are a wide variety of FDA-regulated food products. The list of vehicles for

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<sup>81</sup>Centers for Disease Control and Prevention, NCID: Surveillance Resources: Emerging Infections Program, at <http://www.cdc.gov/ncidod/osr/EIP.htm> (last visited March 7, 2003).

<sup>82</sup>*Id.*

<sup>83</sup>General Accounting Office, *supra* note 18, at 2.

<sup>84</sup>*Id.* at 3.

<sup>85</sup>*Id.* at 3.

“outbreaks due to bacterial etiologies” includes a wide variety of FDA-regulated products including rice, salmon, salad, refried beans and macaroni and cheese.<sup>86</sup> There is a wide variety of prepared foods listed, identifying the fact that a great deal of contamination of these FDA-regulated products takes place during the preparation of the foods.<sup>87</sup> Even a product which meets the FDA’s strict regulations and requirements may become contaminated through its use, and it falls upon various public health organizations, with the assistance of the CDC to use surveillance to monitor the effects that these now-contaminated products have on the American public. One success of the Foodborne Disease Outbreak Surveillance System that is noted in the GAO’s report is that its data helped show “the importance of shell eggs as a source of human infection with *Salmonella* Enteritidis”, a revelation that helped lead to changes in the ways in which the shell eggs were produced and transported and which brought about new FDA regulations for the retail sale of the eggs.<sup>88</sup> This is another prime example of the process in which information from CDC surveillance systems can help bring about new regulations. The Foodborne Disease Outbreak Surveillance System does suffer from some limitations, such as the fact that not all outbreaks are monitored under the system.<sup>89</sup> Another complaint about the Foodborne Disease Outbreak Surveillance System is that it is too slow in releasing data to be very effective.<sup>90</sup> Speed of response is particularly important in responding to outbreaks of disease in order to more quickly find the source of the outbreak and prevent further spread of the pathogen. The delays in the reporting of data from the Foodborne Disease Outbreak Surveillance System are significant.

The General Accounting Office report cited a lag of 3 years for the reporting of information that the system

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<sup>86</sup>Centers for Disease Control and Prevention, Foodborne Outbreak Response and Surveillance Unit, Outbreaks: 2000 Foodborne Diseases Outbreaks Due to Bacterial Etiologies, Foodborne Outbreak Response and Surveillance Unit, at [http://www.cdc.gov/foodborneoutbreaks/us\\_outb/fbo2000/bacterial00.htm](http://www.cdc.gov/foodborneoutbreaks/us_outb/fbo2000/bacterial00.htm) (last visited March 7, 2003).

<sup>87</sup>*Id.*

<sup>88</sup>General Accounting Office, *supra* note 18, at 8-9.

<sup>89</sup>For example, outbreaks stemming from food eaten outside the United States or from drinking water are not included. Sonja J. Olsen, Linda C. MacKinnon, Joy S. Gouling, Nancy H. Bean & Laurence Slutsker, *Surveillance for Foodborne Disease Outbreaks – United States – 1993-1997*, CDC MORBIDITY AND MORTALITY WEEKLY REPORT, March 17, 2000, 3, available at <ftp://ftp.cdc.gov/pub/Publications/mmwr/ss/ss4901.pdf> (last visited March 7, 2003).

<sup>90</sup>General Accounting Office, *supra* note 18, at 3.

gathered for 1997.<sup>91</sup> It is easy to see that this data may be useful for long-term epidemiological studies, but when confronted with a rapidly spreading outbreak or some similar type of public health crisis, data from the system will only really be helpful in the aftermath of such a crisis.<sup>92</sup>

The CDC also has a variety of other surveillance systems that monitor foodborne diseases and FDA-regulated products as part of their overall responsibilities.<sup>93</sup> These include the Botulism Surveillance System which specifically monitors botulism, but which does not restrict those activities to simply foodborne cases of botulism.<sup>94</sup> Given the potential for the use of botulism as a potential agent in bioterrorism, outside of a foodborne source, the system may shift a little of its focus away from foodborne cases. Six different surveillance systems, including FoodNet and PulseNet, but also including electronic reporting systems such as the Public Health Laboratory Information System (PHLIS) and the National Electronic Telecommunications System for Surveillance (NETSS) monitor *Escherichia coli* O157:H7.<sup>95</sup> The same six surveillance systems, also monitor *Salmonella*.<sup>96</sup> For instance, there is the National *Salmonella* Surveillance System, which reports information on *Salmonella* through the electronic reporting system, Public Health Laboratory Information System (PHLIS), one of the six surveillance systems, which is also run by the CDC.<sup>97</sup> Information from the National *Salmonella* Surveillance System provided the basis for the *Salmonella* Outbreak Detection Algorithm (SODA) and the Surveillance Outbreak Detection Algorithm.<sup>98</sup>

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<sup>91</sup>*Id.* at 13.

<sup>92</sup>*Id.* at 13.

<sup>93</sup>*Id.* at 11.

<sup>94</sup>*Id.* at 11.

<sup>95</sup>Centers for Disease Control and Prevention, Division of Bacterial and Mycotic Diseases, *Escherichia coli* O157:H7 – Additional Information: Surveillance, at <http://www.cdc.gov/ncidod/dbmd/diseaseinfo/escherichiacoli.a.htm> (last visited March 7, 2003).

<sup>96</sup>Centers for Disease Control and Prevention, Division of Bacterial and Mycotic Diseases, Salmonellosis – Additional Information: Surveillance, at <http://www.cdc.gov/ncidod/dbmd/diseaseinfo/salmonellosis.a.htm> (last visited March 7, 2003).

<sup>97</sup>Department of Health and Human Services, Centers for Disease Control Prevention, National Center for Infectious Diseases, Division of Bacterial and Mycotic Diseases, Foodborne and Diarrheal Diseases Branch, National Salmonella Surveillance System, Annual Summary, 2001, I, available at <http://www.cdc.gov/ncidod/dbmd/phlisdata/salmtab/2001/SalmonellaAnnualSummary2001.pdf> (last visited March 7, 2003).

<sup>98</sup>*Id.* at II; Department of Health and Human Services, Centers for Disease Control Prevention, National Center for Infectious Diseases, Division of Bacterial and Mycotic Diseases, Foodborne and Diarrheal Diseases Branch, National Salmonella Surveillance System, Annual Summary, 2000, II, available at <http://www.cdc.gov/ncidod/dbmd/phlisdata/salmtab/2000/SalmonellaAnnualSummary2000.PDF> (last visited March 7,

The Surveillance Outbreak Detection Algorithm monitors two specific pathogens, *Salmonella* and *Shigella*, and conducts surveillance to “detect unusual increases in [their]... incidence” to determine if there has been an outbreak of either of the pathogens.<sup>99</sup> The Surveillance Outbreak Detection Algorithm is unique in that it uses statistical data in its surveillance of *Salmonella* and *Shigella*.<sup>100</sup> This system spotlights the benefit of having the CDC conduct surveillance on a nationwide scale in conjunction with state and local agencies. Its ability to compile together data from a variety of different sources enables it to collect a wider field of data, which when compared with the statistical data, enables it to uncover an outbreak where a state or local agency with fewer resources and less data might not.<sup>101</sup>

### III. Surveillance of Antibiotic Resistance

Another major surveillance system that monitors aspects of both foodborne illness and antimicrobial drugs is the National Antibiotic Resistance Monitoring System – Enteric Bacteria (NARMS) that is run jointly by the CDC, FDA, and USDA.<sup>102</sup> NARMS was originally established in 1996, the same year as FoodNet, and it focused upon *Salmonella*.<sup>103</sup> NARMS conducts surveillance from a different approach than PulseNet or FoodNet. NARMS “monitors when foodborne bacteria that can cause disease in humans begin to develop resistance to antimicrobials used in food animals.”<sup>104</sup> The resistance issue is a critical one due to the possible effect of strengthening resistance of the bacteria to antimicrobials. Increased use of antimicrobials in the food

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<sup>99</sup>General Accounting Office, *supra* note 18, at 3.

<sup>100</sup>*Id.* at 10.

<sup>101</sup>*Id.* at 10.

<sup>102</sup>U.S. Food and Drug Administration, Center for Veterinary Medicine, National Antimicrobial Resistance Monitoring System: Enteric Bacteria, August 2002, at <http://www.fda.gov/cvm/index/narms/narmsbro.htm> (last visited March 7, 2003).

<sup>103</sup>*Id.*

<sup>104</sup>U.S. Food and Drug Administration, Food Safety Progress Report, Fiscal Year 2000, August 2001 at <http://www.cfsan.fda.gov/~dms/fsirp004.html> (last visited March 7, 2003).

supply will potentially lead to more difficulty in treating human illnesses with antimicrobials as those illnesses are caused by increasingly drug-resistant strains of bacteria.<sup>105</sup> Surveillance of FDA regulated products in this manner does not attempt necessarily to trace a foodborne illness back to its source, but rather give those in public health organizations a better view of the big picture with regards to bacterial resistance to antimicrobials and the food industry's place in that process. The work that NARMS does involves a variety of FDA-regulated products. Not only does NARMS work involve various types of food animals, from whom samples are taken to determine antimicrobial resistance, but NARMS' work also involves a variety of antimicrobial drugs.<sup>106</sup> There is a division of labor within NARMS, samples from human beings are sent by public health agencies to a CDC laboratory and samples taken from food animals are sent to a USDA laboratory.<sup>107</sup>

#### IV. Surveillance of Vaccines

Food safety is not the only area in which the CDC conducts surveillance of FDA-regulated products. CDC also conducts surveillance of various drugs, particularly vaccines.

One current example of the CDC's surveillance of vaccines is the CDC's surveillance of the current vaccination of government workers with the smallpox vaccine.<sup>108</sup> CDC surveillance monitored the first two "moderate-to-severe events" tied to the vaccination program, one moderate-to severe event and one serious adverse

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<sup>105</sup>U.S. Food and Drug Administration, Food Safety Progress Report, Fiscal Year 2000, *supra* note 104; U.S. Food and Drug Administration, Center for Veterinary Medicine, National Antimicrobial Resistance Monitoring System: Enteric Bacteria, *supra* note 102.

<sup>106</sup>U.S. Food and Drug Administration, Center for Veterinary Medicine, National Antimicrobial Resistance Monitoring System: Enteric Bacteria, *supra* note 102.

<sup>107</sup>*Id.*

<sup>108</sup>Amanda Gardner, *First Moderate Reaction to Smallpox Jab Reported*, DRUG DIGEST, Feb. 27, 2003 at <http://www.drugdigest.org/DD/Articles/News/0,10141,511996,00.html> (last visited March 7, 2003).

event.<sup>109</sup> The surveillance program has already been criticized because all of the severe cases reported have only been found in one state, Florida.<sup>110</sup> The CDC plans to institute a wide ranging telephone survey of 10,000 recipients of the smallpox vaccine to help learn what nonserious side effects there have been, while “clinicians [will] report directly to the CDC” any severe side effects.<sup>111</sup> The survey will be conducted on days 10 and 21 after the individuals have received the vaccine.<sup>112</sup>

#### A. Vaccine Adverse Event Reporting System (VAERS)

The CDC and FDA jointly sponsor a Vaccine Adverse Event Reporting System (VAERS) which performs surveillance on a nationwide scale of various vaccines.<sup>113</sup> VAERS is used as part of the approval process for vaccines and is used to help “identify problems after marketing begins.”<sup>114</sup> VAERS was established in 1990 as a result of the National Childhood Vaccine Injury Act of 1986.<sup>115</sup> The VAERS system also displays another instance of the CDC working in tandem with regulatory agencies. Data reported to VAERS may indicate that there is a “safety risk” with a vaccine, and the CDC may use that data to “detect unusual epidemiological trends and associations” that show a “safety risk”, but only FDA has the power to actually

<sup>109</sup>*Id.*; Centers for Disease Control and Prevention, *Smallpox Vaccine Adverse Events Among Civilians – United States, February 18-24, 2003*, CDC MORBIDITY AND MORTALITY WEEKLY REPORT, Feb. 28, 2003, 156, 157, available at <http://www.cdc.gov/mmwr/PDF/wk/mm5208.pdf> (last visited March 7, 2003).

<sup>110</sup>Gardner, *supra* note 108.

<sup>111</sup>*Id.*; Centers for Disease Control and Prevention, *Notice to Readers: Smallpox Vaccine Adverse Events Monitoring and Response System for the First Stage of the Smallpox Vaccination Program*, CDC MORBIDITY AND MORTALITY WEEKLY REPORT, February 7, 2003, 88, 89, available at <http://www.cdc.gov/mmwr/PDF/wk/mm5205.pdf> (last visited March 7, 2003).

<sup>112</sup>Centers for Disease Control and Prevention, *Notice to Readers: Smallpox Vaccine Adverse Events Monitoring and Response System for the First Stage of the Smallpox Vaccination Program*, *supra* note 111, at 89.

<sup>113</sup>U.S. Food and Drug Administration, *CBER – Vaccine Adverse Effects Reporting System (VAERS)*, at <http://www.fda.gov/cber/vaers/vaers.htm> (last visited March 7, 2003).

<sup>114</sup>Centers for Disease Control and Prevention, *CDC National Vaccine Program Office: Vaccine Fact Sheets*, at [http://www.cdc.gov/od/nvpo/fs\\_tableII.doc2.htm](http://www.cdc.gov/od/nvpo/fs_tableII.doc2.htm) (last visited March 7, 2003).

<sup>115</sup>U.S. Food and Drug Administration, *CBER – Vaccine Adverse Event Reporting System (VAERS): Frequently Asked Questions*, at <http://www.fda.gov/cber/vaers/faq.htm> (last visited March 7, 2003).

recall a vaccine in response to the “safety risk”.<sup>116</sup> Once again, CDC’s surveillance role has an impact on the regulations that are created once the CDC has helped display that a problem exists.

VAERS not only serves a function in helping inform regulatory agencies of the adverse effects of vaccines, but it also serves a public information function. VAERS operates a website that allows members of the public, along with public health organizations and vaccine manufacturers, to see the data on the adverse effects of vaccines that the system contains.<sup>117</sup> This information function is particularly important because members of the public often have questions regarding the safety of the various vaccines that their physicians suggest receiving. Another area in which this public information function is likely to become more important in the future is with regards to highly debated vaccinations against diseases like smallpox, which could be used in terrorist attacks. Both the smallpox and anthrax vaccine have met with a great degree of opposition from a number of parties and information such as that on the VAERS website would give individuals a clearer look at what adverse effects have been reported from the vaccines.

VAERS, unlike FoodNet, is a “passive surveillance system” and as a result, suffers from potential gaps in and problems with its data.<sup>118</sup> Reports to VAERS are “unverified reports of adverse events temporally associated with one or more vaccines.”<sup>119</sup> Potential problems with VAERS data include “limitations of under-reporting, simultaneous administration of multiple vaccine antigens, reporting bias, and lack of incidence rates in unvaccinated comparison groups.”<sup>120</sup> Only a small fraction of reports are made to VAERS in comparison

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<sup>116</sup>*Id.*

<sup>117</sup>Vaccine Adverse Event Reporting System, VAERS – The Vaccine Adverse Event Reporting System, at <http://www.vaers.org> (last visited March 7, 2003). See Centers for Disease Control and Prevention, Surveillance for Safety After Immunization: Vaccine Adverse Even Reporting System (VAERS) – United States, 1991- 2001, at <http://www.cdc.gov/mmwr/preview/mmwrhtml/ss5201a1.htm> (last visited March 7, 2003).

<sup>118</sup>U.S. Food and Drug Administration, CBER – Vaccine Adverse Event Reporting System (VAERS): Information Included in VAERS, at <http://www.fda.gov/cber/vaers/data.htm> (last visited March 7, 2003).

<sup>119</sup>*Id.*

<sup>120</sup>*Id.*

with the total number of doses of vaccines administered each year.<sup>121</sup> Also important is that “no cause and effect relationship has been established” for VAERS reports.<sup>122</sup> However, investigators take the data from VAERS and attempt to determine in which reports of adverse events there was a causal relationship with the vaccine.<sup>123</sup>

All of these issues do at least cast doubt on the VAERS system, and potentially create a problem with the public information function of VAERS. Based on these problems, VAERS data does not necessarily show illnesses and side effects that the vaccines caused, so much as simply showing what the health of the individuals was within a short time period after taking the vaccine. Many members of the public who look at the website’s data concerning the safety of vaccines could potentially equate all negative events to the vaccine, where, in fact, the vaccine may not have caused those effects, and the data will cause unnecessary and unwarranted alarm about the vaccine’s safety. While it is certainly best in these circumstances to err on the side of safety and make the public aware of all adverse events that patients suffer after receiving a vaccine, it should be acknowledged that potentially beneficial vaccines do run the risk of having their reputation in the eyes of the public tainted by negative unrelated data.

Although VAERS is a passive surveillance system, the CDC will, in some instances, conduct limited active surveillance following the administration of a vaccine.<sup>124</sup> With regards to the administration of the smallpox

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<sup>121</sup>Out of approximately 1.9 billion doses of vaccines given from 1991-2001, VAERS received 128,717 reports. *Vaccine Safety: U.S. Adverse Events Compiled For Decade*, VACCINE WEEKLY, Feb. 12, 2003, at 38.

<sup>122</sup>U.S. Food and Drug Administration, CBER – Vaccine Adverse Event Reporting System (VAERS) Information, *supra* note 118.

<sup>123</sup>Out of 602 adverse reports from administration of an anthrax vaccine, investigators narrowed down the information to show six serious adverse events causally related to the vaccine. Maria G. Essig, *Anthrax: Serious Adverse Effects From Anthrax Vaccine Low*, VACCINE WEEKLY, July 31, 2002, at 4.

<sup>124</sup>Centers for Disease Control and Prevention, Smallpox Response Plan and Guidelines (Version 3.0), Annex 4, Vaccine Adverse-Event Reporting, Annex 4-4, (2002), at <http://www.bt.cdc.gov/agent/smallpox/response-plan/files/annex-4.pdf> (last visited March 7, 2003).



vaccine, a “diary report card” will be given to recipients so that they can notify CDC of any reactions following the administration of the vaccine.<sup>125</sup> This differs from passive surveillance because the reports of the recipients are being “actively solicited”.<sup>126</sup>

## V. Reliance of Surveillance Systems on State and Local Public Health Departments

The CDC’s surveillance efforts are largely reliant on the activities of state and local public health departments.<sup>127</sup> Without these agencies reporting cases of illness to the CDC’s systems like FoodNet and PulseNet, those systems would be ineffective. Regardless of whether the surveillance system is active or passive, the efforts of the CDC in surveillance will still greatly rely on state and local public health departments.<sup>128</sup> The CDC’s reliance on data from state public health departments stems in part from the fact that the “states have principal responsibility for protecting the public’s health”.<sup>129</sup> As a result, it is state agencies that will be first notified with the data and reports of foodborne diseases, state agencies that will have the first opportunity to analyze that data, and it will fall upon those state agencies to then pass that information along to the CDC so that they may make use of the data and help coordinate the sharing of that information, through the networks, with other state and local health departments.<sup>130</sup> One small potential exception is the VAERS system, to which anyone may report adverse effects following a vaccination, but this is only a small exception because the overwhelming number of reports to the system are made by physicians and state and local public health departments.

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<sup>125</sup> *Id.* at Annex 4-4.

<sup>126</sup> *Id.* at Annex 4-4.

<sup>127</sup> General Accounting Office, *supra* note 18, at 2.

<sup>128</sup> *Id.* at 1.

<sup>129</sup> *Id.* at 5.

<sup>130</sup> *Id.* at 5.

Another central issue regarding reliance on state public health departments is that state public health departments are often are often limited by what duties their state legislatures have authorized them to perform.<sup>131</sup> The legislatures are unable to keep pace with recent scientific developments, and the public health departments are left to fall behind as well.<sup>132</sup>

Complaints have been cited not just with the CDC's delays in reporting data, but the delays of the state and local agencies in reporting data to the CDC.<sup>133</sup> As noted above, the CDC's surveillance activities are largely dependent on the actions of the state and local public health departments. If state and local agencies do not report data, then even in an active surveillance system like FoodNet, all the CDC can do is call the state agencies and ask for information. These failures in reporting can lead to significant gaps in the information that the network collects. Surveillance systems such as PulseNet and FoodNet are important in part because they allow the various state and local agencies to see information compiled from their counterparts in other jurisdictions. Systems such as FoodNet will not be successful if state and local agencies are unwilling or unable to perform their reporting functions and actively participate. Furthermore, even when states do report, those reports may be incomplete, failing to list an identified pathogen or contaminated food source.<sup>134</sup>

Another difficulty for CDC in creating nationwide networks such as FoodNet and PulseNet is that state and local agencies do not have uniform procedures in reporting their data.<sup>135</sup> For example, different states report different diseases.<sup>136</sup> Uniformity is required for the PulseNet system which needs all laboratories to follow

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<sup>131</sup>David P. Fidler, *Perspectives: Legal Issues Associated With Antimicrobial Drug Resistance*, 4 EMERGING INFECTIOUS DISEASES 169, 170 (April-June 1998), available at <http://www.cdc.gov/ncidod/eid/vol4no2/adobe/fid.pdf> (last visited March 7, 2003).

<sup>132</sup>*Id.*

<sup>133</sup>General Accounting Office, *supra* note 18, at 15.

<sup>134</sup>Reports to FoodNet are not limited to those from foodborne sources. Centers for Disease Control and Prevention, *Preliminary FoodNet Data on the Incidence of Foodborne Illnesses – Selected Sites, United States, 1999*, CDC MORTALITY AND MORBIDITY WEEKLY REPORT, Mar. 17, 2000, 201, 204, available at <http://www.cdc.gov/mmwr/PDF/wk/mm4910.pdf> (last visited March 7, 2003); General Accounting Office, *supra* note 18, at 15.

<sup>135</sup>Centers for Disease Control and Prevention, *Preliminary FoodNet Data on the Incidence of Foodborne Illnesses – Selected Sites, United States, 2001*, CDC MORTALITY AND MORBIDITY WEEKLY REPORT, Mar. 19, 2002, 325, 328, available at <http://www.cdc.gov/mmwr/PDF/wk/mm5115.pdf> (last visited March 7, 2003); General Accounting Office, *supra* note 15, at 16.

<sup>136</sup>General Accounting Office, *supra* note 18, at 16.

the same protocol in order to compare bacterial isolates.<sup>137</sup> There is an inherent difficulty in trying to take various pieces of information from different sources and try to compile it in a standard nationwide network.

## VI. Conclusion

The CDC's surveillance systems, particularly systems such as FoodNet and PulseNet, are invaluable in coordinating and analyzing information from state and local public health departments across the United States. Taking into account the complaints aired with the current operation of the surveillance systems, there is still certainly room for improvement. These improvements will be needed because although incidents of foodborne illnesses have been decreasing, they still take far too great a toll in lives lost each year, and on the national economy as well. The growing threat of bioterrorism also makes these systems, as well as surveillance systems for vaccines, such as VAERS, and current work surrounding the smallpox vaccine, even more important. The increase in funding provided in the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 as well as the continuing efforts of the CDC and state and local health agencies to improve surveillance all provide hope for the future improved operation of these systems.

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<sup>137</sup>Bala Swaminathan, Timothy J. Barrett, Susan B. Hunter, Robert V. Tauxe and the CDC PulseNet Task Force, *supra* note 27, at 388.